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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/724,638      | 12/02/2003  | Gautam Vinod Daftary | 12879/3             | 2014             |

7590

06/30/2006

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EXAMINER

MAIER, LEIGH C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/724,638

**Applicant(s)**

DAFTARY ET AL.

**Examiner**

Leigh C. Maier

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-38 is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/3/04</u> . | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

This application is in condition for allowance except for the formal matters set forth below.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because the oath is not in agreement with the first paragraph of the specification. The declaration states “I hereby claim foreign priority benefits under 35 USC §119(a-d) or §365(b) of any foreign applications ... listed below ...” However, the declaration goes onto state adjacent to the listed documents; “Yes, priority *not* claimed.” Therefore, the plain language states that no foreign priority is being claimed, but the specification states “This application claims priority to Indian provisional application 785/mum/02 filed December 2, 2002 ...” It is further noted that in the event that Applicant does wish to claim priority to these applications, the application numbers for two of these documents are missing.

The specification is objected to because the first paragraph of the specification states “This application claims priority to Indian provisional application 785/mum/02 filed December 2, 2002 ...” and two other documents with missing application numbers. Furthermore, this statement is not in agreement with the declaration, which states that priority is *not* claimed.

The discrepancy between the oath and the specification must be resolved along with appropriate correction, to the specification and/or the oath.

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Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Acknowledgment is made of Applicant's (possible) claim for foreign priority based on an application filed in India on December 2, 2002, although, as noted above, there is some confusion about this claim. It is noted, however, that Applicant has not filed a certified copy of the Indian application as required by 35 U.S.C. 119(b).

***Allowable Subject Matter***

Claims 1-38 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

The claims are drawn to an aqueous composition comprising ifosfamide and 2-hydroxypropyl- $\beta$ -cyclodextrin (2-HP $\beta$ CD) and a method of preparation of said composition. Tait et al (WO 02/02125) teaches an aqueous composition comprising ifosfamide stabilized by a polyol, such as propylene glycol. See abstract and examples. The reference further suggests the addition of underivatized CDs and their ethoxylated derivatives to adjust tonicity. See page 8, at lines 20-24. One of ordinary skill would not be motivated to look beyond the suggested CDs and prepare such a composition comprising 2-HP $\beta$ CD.

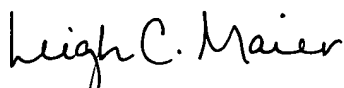
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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Anna Jiang (571) 272-0627, may be contacted. The fax number for Group 1600, Art Unit 1623 is (571) 273-8300.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more. Information regarding the status of an application may be obtained from the Patent Application Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished application is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov> Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.



Leigh C. Maier  
Primary Examiner  
June 23, 2006